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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,446	12/16/2003	Thomas D. Kelly	DI-5928 (112713-457)	8102

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EXAMINER	
DEAK, LESLIE R	
ART UNIT	**PAPER NUMBER**
3761	

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/738,446	KELLY ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-98* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 39-98* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/12/05,11/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 1-13 and 39-98 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4 January 2006.

2. Applicant's election with traverse of the restriction requirement in the reply filed on 4 January 2006 is acknowledged. The traversal is on the ground(s) that all the limitations of claim 14 are present in claim 67 and the limitations of claim 46 are present in claim 91. This is not found persuasive because claim 67 lacks the second pump required by claim 14 and claim 91 lacks the filter within the extracorporeal device required by claim 46.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 14-38 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,470,483 to Bene et al.

In the specification and figures, Bene discloses the device as claimed by applicant. In particular, Bene discloses a device for controlling the balance of fluid in an extracorporeal circuit with a fluid flow path 6, 7, with a medical fluid supply 10, a first pump 11 that adds fluid to the circuit, a blood filtration unit 2, second pump 12 that pulls fluid from the filter, a bypass line 15 that isolates fluid flow from the filtration unit, and a programmable controller 30 (see FIG 1, column 2, lines 33-67). The controller may adjust operation of the pumps and the clamps as required by the system (see column 3, lines 30-40, column 4, lines 60-65), thus rendering the Bene device "operable to," or capable of being operated, in the manner claimed by applicant.

Bene specifically discloses that the disclosed device may isolate the circulating blood from the patient in the extracorporeal circulation loop while delivering a quantity or bolus of substitute liquid to the patient, and that the device is suitable for hemofiltration of hemodiafiltration. The amount of fluid injected into the patient or the length of time of the bypass mode is determined, in part by sensor 19. Sensor 19 is disclosed as providing pressure measurements, but is not limited to pressure measurements. Bene specifically discloses that a graphic recording device in communication with the controller and the circulation system may illustrate a fluid delivery rate deviation of 50mL/hr, indicating that the device comprises blood flow volume sensor, as claimed by applicant (see column 4, lines 60-67, column 5, lines 1-4).

With regard to claims 33-37, Bene discloses that the device is suitable for hemofiltration of hemodiafiltration and illustrates clamps 17 and 18 upstream and downstream of filter 2. The device further includes valve 16 that would allow fluid to

bypass the filtration device. By operating clamps 16 and 18, the medical fluid supply 10 may be delivered upstream or downstream of the blood filtering device 2, and the blood filtering device removes ultrafiltrate from the circuit upstream of the medical fluid entry point.

Applicant presents claims 15-19, 21-32, and 38 drawn to the mode of operation of the claimed device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. In anticipation of applicant's amendment to positively claim the functional limitations of the claimed device, claims 15-19, 21-32, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,470,483 to Bene et al in view of US 6,830,553 to Burbank et al.

In the specification and figures, Bene discloses the device substantially as claimed by applicant, with the exception of various operative modes of the device. Burbank discloses a blood treatment system in which the various pumping, clamping,

and sensing devices on the machine provide fluid management and safety controls by sensing pressure air, temperature. The machine provides other functions, such as priming, supplying a replacement fluid bolus, and rinseback of the person's blood.

With regard to claims 16-18, the device may accept operator input to control the infusion of replacement fluid to a patient, or rely on measured data to determine the infusion, which may be issued as a bolus during a hypotensive period (see column 21, lines 5-10, column 22, lines 37-44).

With regard to claims 21-26, the device disclosed by Burbank performs a rinseback operation at the end of therapy, which is initiated by the controller at the end of the therapy or by the operator (see column 24, lines 40-67, column 31, lines 15-60).

With regard to claims 27-32 and 38, the device disclosed by Burbank performs a prime operation before therapy to remove air, which is initiated by the controller at the beginning of the therapy or by the operator (see column 24, lines 18-38, column 31, lines 15-60). Furthermore, the device comprises an alarm system which may allow the operator to stop the pumps if the sensed conditions vary from preset ranges (see column 26, lines 5-30).

The Burbank device is designed to provide automated and sterile control of a hemofiltration operation that makes frequent hemofiltration more convenient for patients and operators (see column 4, lines 48-59, column 6, lines 35-56). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to program the controller of the Bene device to perform operator-directed or automatic control of bolus delivery, rinseback, alarm, and priming operations, as taught

by Burbank, in order to provide an automated system that makes frequent hemofiltration more sterile and convenient for the patient and operator, as taught by Burbank.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 5,186,431 Tamari

i. Pressure valves for short circuits in extracorporeal circulation

b. US 5,630,946 Hart et al

ii. Blood filtration with short circuits

c. US 6,561,997 Weitzel et al

iii. Extracorporeal circuit with short circuit

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie R. Deak
Patent Examiner
Art Unit 3761
1 March 2006